



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FEB 23 1993

#18

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fisher's Lane, Room 11-44  
Rockville, MD 20857

Dear Mr. Wilson:

The enclosed application for extension of the patent term of U.S. Patent No. 4,219,478 issued on August 26, 1980, was filed on February 11, 1993, under 35 USC § 156.

Your assistance is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is **NOT** to be considered as notice which may be made in the future pursuant to 35 USC § 156 (d)(2)(A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156.

*C. E. Van Horn*

---

Charles E. Van Horn  
Patent Policy & Projects Administrator  
Office of the Assistant Commissioner for Patents

cc: Mark P. Levy, Esq.  
Thompson, Hine & Flory  
2000 Courthouse Plaza, N.E.  
P.O. Box 8801  
Dayton, OH 45401-8801